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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,363	11/15/2001	Richard C. Duke	3923-3	2524

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/16/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,363

Applicant(s)

DUKE ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to therapeutic compositions comprising a dendritic cell, a yeast vehicle, and an antigen, classified in class 424, subclass 93.3.
 - II. Claims 16-22, drawn to methods of making a therapeutic composition, classified in class 424, subclass 93.3.
 - III. Claims 23-25, drawn to methods of eliciting an antigen-specific humoral response and an antigen-specific cell-mediated response by administering a composition comprising a dendritic cell, a yeast vehicle, and an antigen, classified in class 424, subclass 93.3.
 - IV. Claims 26-28, drawn to methods of eliciting an antigen-specific humoral response and an antigen-specific cell-mediated response by administering a composition comprising a yeast vehicle and an antigen, classified in class 424, subclass 93.51.

For Group I above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-IV, and, if Group I is elected, then election is also required to one of inventions IA-IC and to one of inventions I-i to I-viii. The subgroups IA-IC (claims 4, 6, and 8, respectively, linked by claim 1) represent the inventions of Group I wherein:

- IA- the yeast vehicle is loaded intracellularly with an antigen;
- IB- the antigen is covalently or non-covalently attached to the yeast vehicle; or
- IC- the yeast and the antigen are associated by mixing.

The subgroups I-i to I-viii (claim 9) represent the inventions of Group I wherein the antigen is:

- I-i, a viral antigen;
- I-ii, a mammalian cell surface molecule;
- I-iii, a bacterial antigen;
- I-iv, a fungal antigen;
- I-v, a protozoan antigen;
- I-vi, a helminth antigen;

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I-vii, an ectoparasite antigen; or

I-viii, a cancer antigen.

For Group II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-IV, and, if (one of) Group II is elected, then election is also required to one of inventions IIA-IID. These subgroups represent the method of Group II (claims 17, 18, 19, and 20, each linked by claim 16) wherein the yeast vehicle-antigen complex is formed by:

IIA- transfecting the yeast vehicle with a nucleic acid such that it expresses the antigen;

IIB- loading the yeast vehicle with the antigen;

IIC- mixing the yeast vehicle and the antigen; or

IID- physically attaching the antigen to the yeast vehicle.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups IA to IC are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to a composition formed by a different process and having a different structure. As the compositions have different structures and are formed by different processes, they have different modes of operation. The compositions are therefore distinct.

3. The inventions of Groups I-i to I-viii are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to compositions comprising different antigens, and therefore intended to raise immunogenic response against different types of infections. As the composition raise responses against different types of responses, they are achieving different effects. The methods are therefore distinct.

4. The inventions of Groups IIA-IID are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation because these methods have different modes of combining the yeast vehicle and the antigen. As the methods have different modes of operation, they are distinct.

5. The inventions of Groups I-III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to inventions comprising or to methods related to different therapeutic compositions. As the different inventions surround different compositions, they have different modes of operation. The inventions of these Groups are therefore distinct.

6. The inventions of Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making may be used to make any of the various distinct therapeutic compositions. Further, each of the products may be made using any one of the various distinct methods. The products are therefore distinct from the methods of making them.

7. The inventions of Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, since any of the separate compositions within Group I may be used in any of the distinct methods within Group III, the inventions are distinct. Further, the method may be used with either the compositions of Group I, or with the compositions described in the methods of Group IV. Thus, the inventions of these Groups are distinct.

Species Election

8. This application contains claims directed to the several series of patentably distinct species of the claimed inventions described above.

Group I requires election of both the species of yeast used in the invention (claim 14- 9 species) and an election of the type of yeast vehicle used in the composition (claim 15- 5 species). Group I-i (therapeutic compositions with viral antigens) comprises 10 species.

Groups II and IIB each require election of the method of loading used with respect to the loading of the yeast with the antigen (claim 18-7 species) and the loading of dendritic cells with the yeast (claim 16-6 species)

The species are identified below.

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For Group I, if elected, the applicant is required to elect one of the species identified as I-(a) to I-(e), and one of the species identified as I-(1) to I-(9).

The species of I-(a) to I-(e) represent the compositions of Group I wherein the yeast vehicles are selected from:

I-(a) whole yeast cells,

I-(b) yeast sphereoplasts,

I-(c) yeast cytoplasts,

I-(d) yeast ghosts, and

I-(e) subcellular yeast particles.

The species I-(i) to I-(ix) represent the inventions of Group I wherein the yeast vehicle is selected from the yeast genus:

I-(1) *Saccharomyces*,I-(2) *Candida*I-(3) *Cryptococcus*,I-(4) *Hansenula*,I-(5) *Kluyveromyces*,I-(6) *Pichia*,I-(7) *Rhodotorula*,I-(8) *Schizosaccharomyces*, andI-(9) *Yarrowia*.

For Group I-i, if elected, the applicant must elect a viral antigen to be examined. Thus, the applicant must elect one of the claimed compositions wherein the viral antigen is:

I-i-(a) HIV-1 gag,

I-i-(c) HIV-1 pol,

I-i-(e) HIV-1 nef,

I-i-(g) HbcAg,

I-i-(b) HIV-1 env,

I-i-(d) HIV-1 tat,

I-i-(f) HbsAg,

I-i-(h) hepatitis c core antigen,

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I-i-(i) HPV E6 and E7, and

I-i-(j) HSV glycoprotein D.

For Group II, if elected, the applicant must elect one of the following species. These species represent the method of Group II wherein the yeast is loaded into the dendritic cell by:

II-(a) diffusion,

II-(b) active transport,

II-(c) liposome fusion,

II-(d) electroporation,

II-(e) phagocytosis, or

II-(f) bath sonication.

For Group IIB, if elected, the applicant must also elect one of the species IIB-(a) to IIB-(g).

These species represent the method of Group IIB wherein the antigen is loaded into the yeast by:

II-(a) diffusion,

II-(b) active transport,

II-(c) liposome fusion,

II-(d) electroporation,

II-(e) phagocytosis,

II-(f) freeze-thaw cycles, or

II-(g) bath sonication.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The generic claims are identified above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Examiner's Notes

9. It is here noted that in the lists of claims 14 and 18, there is no comma between the last two members of the list. For the purposes of this restriction, the claims have been interpreted as though there were such a comma, and, thus, as though the last two members of the list were intended to be separate embodiments of the claimed inventions. However, if it was intended that the last two members of these lists be part of the same embodiment, it is requested that the applicant state as such in the response to this restriction requirement.

10. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is

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found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

11. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P.

§821.04 regarding the restriction of claims to a product and processes of using the product,

Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of an allowed product claim**. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

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In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Conclusion

12. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

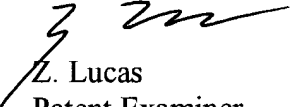
13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

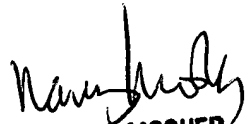
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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
December 2, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600